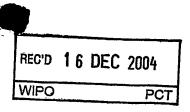
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## PATENT COOPERATION TREATY

## **PCT**



#### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

	(ICI Artele 36 and )	Rule 70)				
Applicant's or agent's file reference PAKIST03139	FOR FURTHER ACTION	SeeNotificationofTransmittalofInternationalPrelim Examination Report (Form PCT/IPEA/416)				
International application No. PCT/KR2003/001427  International filing date(day/month/year) 18 JULY 2003 (18.07.2003)  International Patent Classification (IPC) or national classification and IPC  IPC7 A61K 31/337						
Applicant  KOREA INSTITUTE OF SCI	ENCE AND TECHNOLO	OGY et al				
1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.  2. This REPORT consists of a total of						
Date of submission of the demand		Date of completion of this report				
19 FEBRUARY 2004 (19.02.2004)		16 NOVEMBER 2004 (16.11.2004)				
Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea acsimile No. 82-42-472-7140		zed officer EE, Jae Jeong	CALLID			
	Telepho	ne No. 82-42-481-5604	A1. 112			

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### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International aplication No. PCT/KR2003/001427

I. Ba	sis of the report
1. Wi	th regard to the elements of the international application:*
	the international application as originally filed
X	
<u> </u>	names 1 az
	pages, as originally filed
	pages, filed with the letter of, filed with the demand
X	
	pages, as originally filed
	, as amended (together with any statment) under Arial 10
	pages 37 - 51 , filed with the letter of 23/09/2004
X	the drawings:
<u> </u>	1/2 2/2
	pages, as originally filed
_	filed with the letter of
	the sequence listing part of the description:
	pages, as originally filed
	pages, filed with the letter of, filed with the demand
the The	th regard to the language, all the elements marked above were available or furnished to this Authority in the language in which international application was filed, unless otherwise indicated under this item.  Esse elements were available or furnished to this Authority in the following language English which is the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
. Wi pre	th regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international eliminary examination was carried out on the basis of the sequence listing:  contained inthe international application in written form.
	filed together with the international application in computer readable form.
	furnished subsequently to this Authority in written form.
$\Box$	furnished subsequently to this Authority in computer readable form
$\Box$	The statement that the subsequently formished and the statement that the statement that the subsequently formished and the statement that the statement that the subsequently formished and the statement that the statement that the statement that the subsequently formished and the statement that the statement t
ш	The statement that the subsequently furnished written sequence listing does not go beyond the disc losure in the international applicationas as filed has been furnished.
	The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
X	The amendments have resulted in the cancellation of:
	the description, pages
	X the claims, Nos. 2 - 4, 34 - 36
	the drawings, sheets
	This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**
Replaci in this and 70	cement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to copinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16
Any re	eplacement sheet containing such amendments must be referred to under item I and annexed to this report.
PCT/	TPEA/409 (Box D(July 1908)

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### INTERNATIONAL PRELIMINARY EXAMINATION

International aplication No. PCT/KR2003/001427

V.	V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement						
1.	Statement						
	Novelty (N)	Claims	1, 5-33, 37-73	VPO			
		Claims		YES			
	Inventive step (IS)	<b></b>	1 5 22 25	No			
	mvenuve step (18)	Claims	1, 5 - 33, 37 - 73	YES			
		Claims		NO			
	Industrial applicability (IA)	Claims	1, 5-33, 37-73				
		Claims		YES			
				NO			

Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: WO 0213815 A1 (Hanmi Pharm. Co.) 21 February 2002

D2: WO 0168139 A1 (Korea Institute of Science and Technology) 20 September 2001

D3: WO 0101960 A1 (Lipocine Inc.) 11 January 2001

The amended (23 Sep. 2004) claims 1, 5-32, 72, 73 of the present invention relate to a composition for solubilization of paclitaxel comprising monoolein and oil (which is selected from a group of triglyceride, iodized oil, vegetable oil and animal oil). And the amended (23 Sep. 2004) claims 33, 37-71 of the present invention relate to a composition for solubilization of paclitaxel comprising monoolein, oil (which is selected from a group of triglyceride, iodized oil, vegetable oil and animal oil) and emulsifier.

D1 discloses a composition comprising a drug which is not readily absorbed in the digestive tract (for example, paclitaxel etc.), a compound of formula(I), surfactant (for example, monoglycerides etc.) and oil. D2 concerns a solubilizing composition comprising monoglyceride compound (for example, monoolein etc.), emulsifier, waterinsoluble material (for example, paclitaxel etc.) and organic solvent. D3 describes a pharmaceutical composition comprising a triglyceride, a carrier comprising at least two surfactants and a therapeutic agent (for example, paclitaxel etc.).

Although D1-D3 teach the process for preparing and using various types of compositions comprising a paclitaxel, D1-D3 do not disclose the features of the subject matter of claims 1, 5-33, 37-73, which meet the criteria set forth in PCT Article 33(2), (3) and (4). The composition for solubilization of 0.01-20% by weight of paclitaxel (including emulsifier) comprising 4-90% by weight of monoolein and 0.01-90% by weight of oil (which is selected from a group of triglyceride, iodized oil, vegetable oil and animal oil) is not anticipated by any of the references on record. Thus, the invention described in the present application is considered to be new, inventive and industrially applicable.